

We claim:

1. A diagnostic tool for discriminating between benign and malignant disease, said tool comprising a indicator ratio selected from the group consisting of the concentration ratios:
 - a) IGF/kallikrein-like protein,
 - b) IGFBP/kallikrein-like protein,
 - c) IGF/IGFBP/kallikrein-like protein,
 - d) (intact IGFBP/total IGFBP)/kallikrein-like protein, and
 - e) (IGF + IGFBP)/kallikrein-like protein.
2. The diagnostic tool of claim 1, said tool comprising a indicator ratio selected from the group consisting of :
 - a) IGF-I/free PSA,
 - b) intact IGFBP-3/free PSA,
 - c) (IGF-I/total IGFBP-3)/free PSA,
 - d) (intact IGFBP-3/total IGFBP-3)/free PSA,
 - e) (IGF-I + intact IGFBP-3)/free PSA, and
 - f) intact IGFBP3.
3. The diagnostic tool of claim 1, wherein said tool is used to distinguish between benign conditions and lung cancer, breast cancer, colon cancer or prostate cancer.
4. The diagnostic tool of claim 1, wherein said tool is used to distinguish between benign conditions and prostate cancer.

1 5. A method of predicting cancer in a patient, comprising determining an indicator ratio selected
2 from the group consisting of the concentration ratios of:

- 3 a) IGF/kallikrein-like protein,
4 b) IGFBP/kallikrein-like protein,
5 c) IGF/IGFBP/kallikrein-like protein,
6 d) (intact IGFBP/total IGFBP)/kallikrein-like protein, and
7 e) (IGF + IGFBP)/kallikrein-like protein,

8 whereby a indicator ratio different from a standard normal value indicates the existence of cancer.

6. The method of claim 5, wherein the indicator ratio is selected from the group consisting of:

- 1 a) IGF-I/free PSA,
2 b) intact IGFBP-3/free PSA,
3 c) (IGF-I/total IGFBP-3)/free PSA,
4 d) (intact IGFBP-3/total IGFBP-3)/free PSA,
5 e) (IGF-I + intact IGFBP-3)/free PSA, and
6 f) intact IGFBP3.

1 7. The method of claim 5, wherein the indicator ration is used to distinguish between benign
2 conditions and lung cancer, breast cancer, colon cancer or prostate cancer.

1 8. The method of claim 5, wherein said indicator ratio is used to distinguish between benign
2 conditions and prostate cancer.

3 9. The method of claim 8, wherein the method further includes a measurement of free/total PSA.

- 1 10. A method of monitoring cancer in a patient, comprising determining an indicator ratio
2 selected from the group consisting of concentration ratios of:
3 a) IGF/kallikrein-like protein,
4 b) IGFBP/kallikrein-like protein,
5 c) IGF/IGFBP/kallikrein-like protein,
6 d) (intact IGFBP/total IGFBP)/kallikrein-like protein, and
7 e) (IGF + IGFBP)/kallikrein-like protein,
8 whereby a change in the indicator ratio indicates progression of the cancer.
11. The method of claim 10, wherein the indicator ratio is selected from the group consisting of
a) IGF-I/free PSA,
b) intact IGFBP-3/free PSA,
c) (IGF-I/total IGFBP-3)/free PSA,
d) (intact IGFBP-3/total IGFBP-3)/free PSA,
e) (IGF-I + intact IGFBP-3)/free PSA, and
f) intact IGFBP3.
12. The method of claim 10 wherein the cancer is selected from the group consisting of lung
cancer, colon cancer, breast cancer and prostate cancer.
13. The method of claim 11, wherein the cancer is prostate cancer.
14. The method of claim 13, wherein the method further includes a measurement of free/total
PSA.

1 15. A method of predicting cancer in a patient, comprising measuring at least two IGF axis
2 components and a tumor marker.

1 16. The method of claim 15, wherein the IGF axis components are selected fro the group
2 consisting of IGF-I, IGF-II, IGFBP-1, IGFBP-2, IGFBP-3, IGFBP-4, IGFBP-5, IGFBP6,
3 IGFBP-rP-1, IGFBP-rP-2, IGFBP-rP-3, IGFBP-rP-4, IGFBP-rP-5, IGFBP-rP-6, IGFBP-rP-
4 7, IGFBP-rP-8, IGFBP-rP-9, IGFBP protease, GH, GHBP, GH receptor, IGF receptor, IGF
5 proteases, ALS, IGF receptor antagonists, and GH receptor antagonists and wherein the
6 tumor marker is selected from the group consisting of PSA, kallikrein, S-100 protein, C219,
7 GCDFP-15/gp17, riboflavin carrier protein, vitamin carrier proteins, human chorionic
8 gonadotropin, alpha-fetoprotein, lactate dehydrogenase, cytokeratin 19 fragment, CYFRA
9 21-1, carbohydrate antigen 19.9, macrophage-colony stimulating factor, abnormal
10 prothrombin PIVKA-II, tissue polypeptide antigen, carcinoembryonic antigen, cancer antigen
11 125, CA72-4, CA15-3, squamous cell antigen, neuron specific enolase, focal adhesion kinase,
12 soluble CD44 (sCD44), soluble CD30 (sCD30), tissue polypeptide specific antigen (TPSA),
13 total alkaline phosphatase (T- ALP), urinary Dpd/creatinine (Cre) ratios, bone specific
14 alkaline phosphatase (B-ALP), N-acetylneuraminic (Neu5Ac), vascular endothelial growth
15 factor (VEGF), glutathione peroxidase, melanoma antigen (MAGE), mesothelin and
16 megakaryocyte potentiating factor (MPF), cyclin-dependent kinase inhibitor p27 (Kip1),
17 PGP9.5, proliferating cell nuclear antigen (PCNA), Cyclin D1, epidermal Growth Factor
18 (EGF), transforming growth factor alpha (TGF alpha), estrogen receptor-related protein
19 (ERRP), multidrug resistance marker (MDRM), protein kinase C (PKC), Gs alpha, inhibin,
20 cathepsin D, H19, the steroid hormones, p53, and cytokines and interleukins.